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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,769	08/14/2001	Wei-Qiang Gao	P5007R1	9616

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,769	GAO ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003 and 30 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date [illegible].
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed April 30, 2004 is acknowledged and has been entered.

2. The amendment filed November 24, 2003 is acknowledged and has been entered. Claims 3-7 and 12-15 have been amended.

3. Receipt of the following submissions filed November 24, 2003 is acknowledged:

(a) Petition to Correct Inventorship under 37 CFR 1.48(a);

(b) Consent of Assignee under 37 CFR 1.48(a)(4);

(c) Declaration of Mark T. Kresnak, Ph.D. Regarding Material Deposited under ATCC Accession No. 203651;

(d) Combined Declaration for Patent Application and Power of Attorney;

(e) Statement of Thomas D. Wu under 37 CFR 1.48(a)(1);

(f) Statement of Zemin Zhang under 37 CFR 1.48(a)(1);

(g) Statement of Robert Soriano under 37 CFR 1.48(a)(1).

(h) Statement of P. Mickey Williams under 37 CFR 1.48(a)(1).

(i) Statement of Jianyong Shou under 37 CFR 1.48(a)(1).

(j) Statement of Victoria Smith under 37 CFR 1.48(a)(1);

(k) Statement of Paul Polakis under 37 CFR 1.48(a)(1);

(l) Statement of William I. Wood under 37 CFR 1.48(a)(1);

(m) Statement of Colin K. Watanabe under 37 CFR 1.48(a)(1);

(n) Statement of Austin Gurney under 37 CFR 1.48(a)(1);

(o) Statement of Audrey Goddard under 37 CFR 1.48(a)(1); and

(p) Application Data Sheet.

4. Claims 1-15 are pending in the application and are currently under prosecution.

Inventorship

5. In view of the papers filed November 24, 2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the deletion of Paul Polakis, Jianyong Shou, Victoria Smith, Robert Soriano, P. Mickey Williams, Thomas D. Wu, and Zemin Zhang, and by the addition of Audrey Goddard, Austin Gurney, Colin Watanabe, and William Wood.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Information Disclosure Statement

6. The information disclosure statement filed August 29, 2003 has been placed in the application file. A reference to the information contained therein will not be published, as the information has not been set forth in a manner that would permit the public to attain said information, e.g., published or archived in a publicly retrievable manner. While it is apparent the information disclosed therein is the result of different BLAST searches, the Examiner cannot readily ascertain which sequence has been used as a query, how the search was actually performed, and whether any of the result of search is relevant to the instantly claimed subject matter.

Priority

7. Applicant has complied with the requirements set forth under 35 USC § 120 to properly claim the benefit of the earlier filing dates of PCT/US99/28551

filed December 2, 1999, PCT/US99/28634 filed December 1, 1999, and US Provision Application No. 60/119,537. The earliest effective filing date of the instant application is therefore February 10, 1999.

Grounds of Objection and Rejection Withdrawn

8. Unless specifically reiterated below, Applicant's amendments filed November 24, 2003 and April 30, 2004 have obviated the grounds of objection and rejection set forth in the previous Office action mailed July 14, 2003.

Response to Amendment

9. The amendment filed April 30, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is: "which applications are incorporated herein by reference", wherein said application are PCT/US99/28551, PCT/US99/28634, and US Provisional Application No. 60/119,537. An incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. See 35 U.S.C. § 132(a). When a benefit claim is submitted after the filing of an application, the reference to the prior application cannot include an incorporation-by-reference statement of the prior application. Therefore, the incorporation-by-reference statement in the amendment to the specification introduces new matter and renders the amendment improper. See *Dart Industries v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980). See 1268 OG 89 (18 March 2003).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

> enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

The claims are drawn to a genus of antibodies that bind a genus of polypeptides having an amino acid sequence that is at least 80% identical to the amino acid sequence set forth as SEQ ID NO: 7. However, the specification fails to provide an adequate written description of the genus of polypeptides to which the claimed antibodies bind, and therefore the specification fails to provide an adequate written description of the claimed genus of antibodies.

While the specification has adequately described the polypeptide of SEQ ID NO: 7, the specification fails to describe the structural and functional features of at least a substantial number of the members of the genus of variant of the polypeptide of SEQ ID NO: 7 to which the claimed antibodies bind, such that the skilled artisan could immediately envision, recognize, or distinguish at least a substantial number of those variants, and thus the claimed antibodies that bind those variants. For example, although the specification describes SEQ ID NO: 7, the specification fails to disclose the particularly identifying structural and functional features that are common to both the polypeptide of SEQ ID NO: 7 and the members of the genus of variants; so, the disclosure of SEQ ID NO: 7 cannot be regarded as descriptive, or representative of the genus of claimed variants. Moreover, the specification fails to describe which amino acids of the amino acids sequence set forth as SEQ ID NO: 7 can be replaced, and by which other amino acids, such that the resultant variant retains the structure and functional characteristics of the polypeptide of SEQ ID NO: 7. Therefore, the written description would not reasonably convey to the skilled artisan that Applicant had

possession of at least a substantial number of the polypeptides to which the claimed antibodies bind at the time the application was filed, and therefore would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

The instant written description of the claimed invention would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed, because Skolnick et al. (*Trends in Biotechnology* **18**: 34-39, 2000) discloses that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see, e.g., the abstract; and page 34, *Sequence-based approaches to function prediction*). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see, in particular, the abstract and Box 2). Thus, one skilled in the art would not accept the assertion, which is based only upon an observed similarity in amino acid sequence, that a variant of the polypeptide of SEQ ID NO: 7 is capable of functioning the same, or even as having the same structure as the polypeptide of SEQ ID NO: 7. Bowie et al. (*Science* **257**: 1306-1310, 1990) teaches that an amino acid sequence encodes a message that determines the shape and function of a protein; and, that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome. Bowie et al. teaches that the determination of protein structure from sequence data and, in turn, utilizing structural determinations to ascertain functional aspects of the protein is extremely complex (page 1306, column 1). Even if the skilled artisan were able to submit a complete list of the possible nucleic acids and the proteins encoded thereby, which fall within the scope of the claims, the skilled artisan could not recognize which of these would function similarly to a protein comprising SEQ ID NO: 7, and which would not.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

In addition, in deciding *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the Court held that a generic statement that defines a genus of nucleic acids *by only their functional activity* does not provide an adequate written description of the genus. By analogy, a generic statement that defines a genus of antibodies by only their common ability to bind the polypeptide of SEQ ID NO: 7 or a variant thereof does not serve to adequately describe the genus as whole. The Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for

> patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-9 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. US 2002/0164646 A1.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US Patent Application Publication No. US 2002/0164646 A1 (Botstein et al.) teaches an isolated antibody that binds to a polypeptide comprising an amino acid sequence having at least 80% identity to the amino acid sequence set forth in SEQ ID NO: 7, or which binds to a polypeptide comprising an amino acid sequence that is at least 80% identical to an amino acid sequence encoded by the cDNA deposited under ATCC Deposit No. 230651, i.e., the cDNA clone DNA77631-2537; see entire document (e.g., SEQ ID NO: 22; page 14, paragraph [0209], through page 16, paragraph [0227]; page 71, paragraph [0757]. Additionally, Botstein et al. teaches that the antibody can be intact or an engineered fragment, chimeric or humanized, monoclonal or polyclonal, and/or conjugated to a growth inhibitory agent, namely a cytotoxic agent, namely a toxin or radioisotope, which conjugate is growth inhibitory and induces death of a cell to which it binds; see, e.g., page 17, paragraph [0252]; page 51, paragraph [0505], through page 52, paragraph [0508]. Botstein et al. teaches that once isolated a DNA molecule encoding the antibody can be placed in a vector, which can then be transfected into host cells, namely CHO cells to produce the antibody, or into bacterial cell, such as *E. coli*; see, e.g., page 49, paragraph

[0485]; and page 17, paragraph [0250]. Furthermore, Botstein et al. teaches the antibody can be detectably labeled; see, e.g., page 26, paragraph [0340].

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1, 2, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent Application Publication No. US 2002/0164646 A1 in view of Liu et al. (*Proc. Natl. Acad. Sci. USA* **93**: 8618-8623, 1996) (or record).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US Patent Application Publication No. US 2002/0164646 A1 (Botstein et al.) teaches that which is set forth above in the rejection under 35 USC § 102(e).

In addition, Botstein et al. teaches the polypeptide to which the antibody binds, i.e., PRO3434 (SEQ ID NO: 22), is over-expressed in lung, colon, and breast cancer; see, e.g., page 60, paragraph [0615]. Botstein et al. teaches their results indicate that the polypeptide is a useful target for therapeutic intervention in certain cancers such as colon, lung, breast and other cancers; and moreover, Botstein et al. teaches a therapeutic agent may take the form of an antagonist of PRO3434, which is, for example, a humanized antibody that binds the polypeptide (page 60, paragraph [0615]). Botstein et al. teaches the antibody or conjugate thereof comprising a cytotoxic agent can be formulated as a pharmaceutical composition and administered to a patient to treat various disorders; see, e.g., page 52, paragraph [0513], through page 53, paragraph [0520]; page 51, paragraph [0504].

Although Botstein et al. teaches the antibody can be conjugated to a chemotherapeutic agent for use in treating cancer, Botstein et al. does not expressly teach that the chemotherapeutic agent to which the antibody is conjugated can be maytansinoid.

Liu et al. teaches eradication of large colon tumors in xenograft animal models by the targeted delivery of maytansinoid to the tumors by administering to the animal a conjugate of antibody that bids an antigen expressed by various tumors and the maytansinoid drug DM1; see entire document (e.g., the abstract).

It would have been *prima facie* obvious to one ordinarily skilled in the art at the time of the invention to have conjugated the antibody of Botstein et al. to the maytansinoid drug DM1 for use in treating colon cancer, because Botstein et al. teaches that an immunoconjugate comprising an antibody that binds PRO3434, which is a protein antigen over-expressed in colon cancer, and a cytotoxic drug can be used effectively to treat colon cancer and Liu et al. teaches the targeted delivery of the chemotherapeutic maytansinoid drug DM1 by an immunoconjugate can eradicate even large colon tumors. One ordinarily skilled

in the art at the time of the invention would have been motivated to do so to treat colon cancer.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-3 and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of copending Application No. 10/439,249. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter encompassed by the claims of the instant and copending applications is nearly the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-3 and 5 are directed to the same invention as that of claims 18 and 19 of commonly assigned copending Application No. 10/439,249. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

19. Claims 1-3 and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of copending Application No. 10/032,990. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter encompassed by the claims of the instant and copending applications is nearly the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1-3 and 5 directed to the same invention as that of claims 18 and 19 of commonly assigned copending Application No. 10/032,990. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no

effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
July 19, 2004

SUPERVISORY PATENT EXAMINER
TC 1600
7/21/04